Supreme Court, U.S.
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No. 94-1754

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1994

DOROTHY MARIE REEVES,
Petitioner,

vs.

ACROMED CORPORATION
and
ST. PAUL FIRE & MARINE INSURANCE COMPANY,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITIONER'S REPLY BRIEF

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ARGUMENT IN REPLY

Respondents seek to paint a picture of intercircuit uniformity by urging that there is "extensive control over the contents of prescription device labeling" by the FDA and that because of this "the Federal Appellate Courts have unanimously held that failure-to-warn claims are preempted when brought against manufacturers of prescription medical devices." See Respondents' Brief in Opposition to Certiorari at p. 8. This assertion is incorrect.

The contents of labels for prescription are not "extensively" regulated. *See* 21 *C.F.R.* §801.109. Moreover, two federal circuit courts have expressly ruled that failure to warn claims with regard to prescription devices are not preempted where, as here, the device was cleared for market subject to Class II regulations and there were no specific labeling regulations applicable to it.[1] Finally, none of the decisions cited by respondents has held that the regulations governing the labeling of prescription devices were, in and of themselves, a sufficient basis for preemption of state law failure-to-warn claims. Rather, they have ruled that premarket approval,[2] IDE approval,[3] or special, device specific labeling regulations[4] are "specific requirements" under 21 *U.S.C.* §360k(a) which preempt state law tort law claims, including but not limited to failure to warn claims.

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[1] *Anguiano v. E.I. DuPont De Nemours & Co., Inc.*, 44 F.3d at 809-811 (9th Cir. 1995); *Lamontagne v. E.I. DuPont De Nemours & Co.*, 41 F.3d at 846, 853-55 (2d Cir. 1994).

[2] *Michael v. Shiley*, 46 F.3d 1316 (3d Cir. 1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. den.*, 114 S.Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993), *cert. den.*, 114 S.Ct. 84 (1993); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994).

[3] *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir. 1994); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994) *(per curiam)*; *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992).

[4] *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir.), *rehearing denied*, 873 F.2d 297 (1989).

However, the appellate precedents have also held that clearance to market pursuant to a section 510k premarket notification is an inadequate basis for preemption[5]; that claims arising from devices cleared for market as Class II devices are not preempted in the absence of a device specific regulation[6]; that preemption cannot be based on the FDA's failure to enact available regulatory controls with respect to a given device[7]; and that there is no preemption of claims arising from conduct in violation of the federal law governing medical devices.[8] Respondents do not deny that these principles have been announced in decisions by the Circuit Courts of Appeal or State Supreme Courts. Respondents do not deny that the Fifth Circuit's Opinion in the present case effectively repudiates each of these principles. And they do not deny that conflict over the proper resolution of these issues will lead to further confusion in an area of the law in which respondents themselves concede that "the appellate courts are arguably divided." See Respondents' Brief in Opposition to Certiorari at p. 10.

Plainly, this confusion arises from the absence of any applicable precedent from this Court on the issue of medical device preemption. As it has done in so many other areas where federal preemption has become a concern[9], we respectfully submit that

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[5] *Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 650, 837 P.2d 1273, 1282 (1992). *See also, National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 998 (8th Cir. 1994); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1423 n. 6 (5th Cir.) *cert. den.*, 114 S.Ct. 86 (1993).

[6] *Anguiano*, 44 F.3d at 809-811 (9th Cir. 1995); *Lamontagne*, 41 F.3d at 853-55 (2d Cir. 1994).

[7] *Freightliner Corp. v. Myrick*, 1995 WL 224617 (U.S., April 18, 1995); *National Bank of Commerce*, 38 F.3d at 997; *Lamontagne* 41 F.3d at 853-854 & 855.

[8] *National Bank of Commerce*, 38 F.3d at 993; *Michael*, 46 F.3d at 1327-28; *Slater*, 961 F.2d at 334.

[9] *See e.g., Freightliner Corp. v. Myrick*, 1995 WL 224617 (U.S., April 18, 1995); *American Airlines, Inc. v. Wolens*, 115 S.Ct. 817 (1995); *CSX Transportation, Inc. v. Easterwood*, 113 S.Ct. 1732 (1993); *Cipollone v. Liggett Group, Inc.* 112 S.Ct. 2608 (1992).

this Court should accept certiorari here to settle the question of preemption in the important field of medical device liability.

Respectfully submitted,

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